PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Scott AROUTH, et al.	)	
	)	
Divisional of	)	
Serial No.: 09/611,220	)	Group Art Unit: 1631
	)	
Predecessor Application	)	
Filed: July 6, 2000	)	Examiner: Allen, M.
	)	
For: **NEURAL-NETWORK-BASED IDENTIFICATION, AND APPLICATION, OF GENOMIC INFORMATION PRACTICALLY RELEVANT TO DIVERSE BIOLOGICAL AND SOCIOLOGICAL PROBLEMS, INCLUDING DRUG DOSAGE ESTIMATION**	)	
	)	
Atty's Docket No.: DIA 0002DIV	)	
	)	

San Diego, California
February 11, 2002

PRELIMINARY AMENDMENT UNDER 37 C.F.R. §115 TO THE DIVISIONAL PATENT APPLICATION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

The present application is a divisional of predecessor application serial No.: 09/611,220 filed July 6, 2000.

Please preliminarily amend the present divisional patent application as follows:

In The Claims

At page 1, line 9, after "application." insert --The present application is also a divisional of U.S. patent application serial number 09/611,220 filed July 6, 2000, of the same name and to the same inventors.--, and at line 9 replace "application' (second occurrence) with --applications--.

A copy of page 1 as amended is attached.

In The Claims

Please cancel claims 1-10, 12-13 and 16-26 without prejudice as being directed to un-elected inventions. Please amend claims

14, 15. Please add claims 27-35.

Copes of the claims as amended in (i) amendatory and (ii) plain text form are attached.

REMARKS

Claims 11, 14-15, and 27-35 are in the application. Consideration and substantive examination are respectfully requested.

1. A Requirement for Restriction Under 35 U.S.C. §121, and the Applicants' Response Thereto in The Predecessor Patent Application

A Requirement for Restriction Under 35 U.S.C. §121 was made in the predecessor application serial No.: 09/611,220 between the following inventions:

I. Claims 1-6, drawn to a computerized method of identifying a statistically significant group of datums, classified in at least class 702, subclass 19 and class 706, subclass 15.

II. Claims 7-8, drawn to a method of identifying clinically relevant alleles, classified in at least class 702, subclass 21 and class 706, subclass 15.

III. Claims 9 and 14-15, drawn to a method for predicting an adverse reaction, classified in at least class 702, subclass 19 and class 706, subclass 15.

IV. Claims 10 and 14-15, drawn to a method for predicting optimal drug dosage, classified in at least class 702, subclass 19 and class 706, subclass 15.

V. Claims 11 and 14-15, drawn to methods of identifying suitable therapy, classified in at least class 702, subclass 19 and class 706, subclass 15.

VI. Claims 12 and 14-15, drawn to methods of identifying and predicting susceptibility to disease, classified in at least class 702, subclass 19 and class 706. subclass 15.

VII. Claims 13 and 14-15, drawn to methods of predicting at

least one clinical result, classified at least class 702, subclass 19 and class 706, subclass 15.

VIII. Claims 16-18, drawn to methods of training a neural net, classified in at least class 702, subclass 19 and class 706, subclass 15.

IX. Claims 19-20, drawn to methods of reducing computational cost and complexity, classified in at least class 702, subclass 19 and class 706, subclass 15.

X. Claim 21, drawn to a method of predicting drug interactions, classified at least class 702, subclass 19 and class 706, subclass 15.

XI. Claims 22-26, drawn to methods of identifying a set of universal functional categories of genomic information, classified at least class 702, subclass 19 and class 706, subclass 15.

Of these inventions, Applicants elected **without** traverse the Invention of Group IV, claims 10 and 14-15. There is **no** change of inventorship.

2. Claims of the Present Divisional Patent Application

In the present divisional patent application Applicants now seek examination of the invention of Group 5, claims 11 and 14-15.

Applicants understand that claims 14-15 will be examined only to the degree that they reflect the elected method of claim 11.

Furthermore, Applicants have added claims 27-35. Applicants maintain that of these added claims, claims 27-28 and 29 are drawn to methods of identifying suitable therapy, classified in at least class 702, subclass 19 and class 706, subclass 15, and are thus suitably grouped, and examined, with claims 10 and 14-15.

Furthermore, claims 30-35 are directed to a neural network performing the method and/or on which the method is performed,

and are thus suitably examined with the other claims.

3. Summary

In consideration of the preceding amendment and accompanying remarks, the present divisional patent application is deemed in condition for substantive examination. The timely action of the Examiner to that end is earnestly solicited.

Applicant's undersigned attorney is at the Examiner's disposal should the Examiner wish to discuss any matter which might expedite prosecution of this case.

Sincerely yours,

William C. Fuess

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[X] Attorney of Record
[ ] Filed Under 37 CFR §1.34(a)

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that these documents and the associated divisional patent application are being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee" mailing Label Number ET655458786US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231, ATTN: Box Patent Application on the date written below.

February 11, 2002	William C. Fuess	William C. Fuess
Date	Typed Name of Person Mailing Correspondence	Signature of Person Mailing Correspondence

CLAIMS (AS AMENDED)

11. (Restated) A method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism,

the method particularly serving to identify a relationship between, on a one hand, at least one therapy for at least one disease of an organism, and, on the other hand, genomic data of the organism in the form of two or more alleles and/or SNP pattern(s) of the organism

the method still more particularly serving to determine which of a large number of alleles as variously occur in the genomic data of a large number of individual organisms are, in actual fact, relevant, both individually and in combination, to certain biological and social variables of these organisms, including the efficacy of at least one therapy to at least one disease of these organisms,

the method comprising:

1) constructing a neural network suitable to map (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms as inputs to (ii) historical incidences of responses to therapies for diseases of the individual organisms as outputs; and

2) training the constructed neural network on numerous examples of (i) genomic data as corresponds to (ii) historical incidences of responses to therapies for the diseases of, a multiplicity of individual organisms so as to make a trained neural network that is fit, and that possesses a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms; and

3) exercising the trained constructed neural network in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the neural network was trained, in order to identify a relationship between the particular therapy and genomic data, in the form of two or more alleles, of the organisms.

14. (Amended) The method according to claim[s 9, 10,] 11[, 12 or 13]

wherein the training is automated by computerized programmed operations using a genetic algorithm.

15. (Amended) The method according to claim[s 9, 10,] 11[, 12 or 13]

wherein the training is automated by computerized programmed operations using a genetic algorithm reduced in computational complexity by including the steps of:

grouping alleles and/or characteristic SNP patterns into families as are defined by (i) having similar expression patterns or (ii) being turned on and off by another gene, or (iii) both having similar expression patterns and being turned on and off by the same gene; and

starting training of the neural network with the genetic algorithm by using the families so created as single inputs to the neural network, the training with the genetic algorithm continuing repetitively until, families of greater and lessor significance being identified, it becomes computationally possible to train the neural network to genomic data consisting of individual alleles and/or characteristic SNP patterns;

wherein partitioning of all alleles and/or characteristic SNP patterns into families permits training of the neural network in a hierarchy of stages, first to the families and only then to the individual alleles and/or characteristic SNP patterns.

27. (Added) The method according to claim 11 that, at a time before the training of the constructed neural network on numerous examples further comprises:

obtaining, as a first portion of the numerous examples upon which the constructed neural network is trained, (i) genomic data in the form of alleles datums of types taken from a first group consisting essentially of

entire gene families,

specific alleles,

specific base pair sequences,
locations and types of introns, and
nucleotide polymorphism,

plus at least one member of a second, environmental, group consisting essentially of

diet type,
home region,
occupation,
viral levels,
peptide levels,
blood plasma levels, and
pharmacokinetic and pharmacodynamic parameters.

28. (Added) The method according to claim 27 wherein the obtaining, as a first portion of the numerous examples upon which the neural network is trained, (i) genomic data in the form of alleles datums from a third, combination genetic and environmental, group consisting essentially of

ethnicity, and
race.

29. (Added) A computerized method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism, the method comprising:

constructing a neural network relating as inputs (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms to outputs in the form of (ii) historical incidences of responses to therapies for diseases of the same individual organisms; and

training the neural network so constructed on numerous (i) genomic datums, as correspond to (ii) historical incidences of responses to therapies for the diseases, of a multiplicity of individual organisms;

therein making a trained neural network that is fit, and that possesses a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the

organisms; and

exercising the trained constructed neural network in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the neural network was trained, in order to identify a relationship between a particular therapy and the genomic data, in the form of two or more alleles, of an individual organism;

wherein from the identified relationship it is determinable whether the particular therapy is suitable for the individual organism.

30. (Added) A neural network

suitable to map (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms as inputs to (ii) historical incidences of responses to therapies for diseases of the individual organisms as outputs; and

trained on numerous examples of (i) genomic data as corresponds to (ii) historical incidences of responses to therapies for the diseases of, a multiplicity of individual organisms so as to be fit, and to possesses a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms;

wherein the trained neural network is exercisable in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the neural network was trained, in order to identify a relationship between the particular therapy and genomic data, in the form of two or more alleles, of the organisms.

31. (Added) The trained neural network according to claim 30

trained by computerized programmed operations using a genetic algorithm.

32. (Added) The trained neural network according to claim 30

trained by computerized programmed operations using a genetic algorithm is reduced in computational complexity by including the

steps of:

grouping alleles and/or characteristic SNP patterns into families as are defined by (i) having similar expression patterns or (ii) being turned on and off by another gene, or (iii) both having similar expression patterns and being turned on and off by the same gene; and

starting training of the neural network with the genetic algorithm by using the families so created as single inputs to the neural network, the training with the genetic algorithm continuing repetitively until, families of greater and lessor significance being identified, it becomes computationally possible to train the neural network to genomic data consisting of individual alleles and/or characteristic SNP patterns;

wherein partitioning of all alleles and/or characteristic SNP patterns into families permits training of the neural network in a hierarchy of stages, first to the families and only then to the individual alleles and/or characteristic SNP patterns.

33. (Added) The trained neural network according to claim 30 that is trained on the numerous examples

obtained, in a first portion, from (i) genomic data in the form of alleles datums of types taken from a first group consisting essentially of

entire gene families,
specific alleles,
specific base pair sequences,
locations and types of introns, and
nucleotide polymorphism,

plus at least one member of a second, environmental, group consisting essentially of

diet type,
home region,
occupation,
viral levels,
peptide levels,
blood plasma levels, and

pharmacokinetic and pharmacodynamic parameters.

34. (Added) The trained neural network according to claim 33 that is trained on the numerous examples

further obtained, still in the first portion, from (i) genomic data in the form of alleles datums of types taken from a third, combination genetic and environmental, group consisting essentially of

ethnicity, and

race.

35. (Added) A neural network functioning to identify from the genomic data of an individual organism a suitable therapy for at least one disease of the organism, the neural network

relating as inputs (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms to outputs in the form of (ii) historical incidences of responses to therapies for diseases of the same individual organisms; and

being trained on numerous (i) genomic datums, as correspond to (ii) historical incidences of responses to therapies for the diseases, of a multiplicity of individual organisms; and, by virtue of so relating and of being sot trained

being fit, meaning possessing a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms when exercised in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the training was directed, in order to identify a relationship between a particular therapy and the genomic data, in the form of two or more alleles, of an individual organism;

wherein from exercising of the trained neural network possessing the measure of goodness on the identified relationship it is determinable whether the particular therapy is suitable for the individual organism.

CLAIMS (IN PLAIN TEXT FORM)

11. (Restated) A method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism,

the method particularly serving to identify a relationship between, on a one hand, at least one therapy for at least one disease of an organism, and, on the other hand, genomic data of the organism in the form of two or more alleles and/or SNP pattern(s) of the organism

the method still more particularly serving to determine which of a large number of alleles as variously occur in the genomic data of a large number of individual organisms are, in actual fact, relevant, both individually and in combination, to certain biological and social variables of these organisms, including the efficacy of at least one therapy to at least one disease of these organisms,

the method comprising:

1) constructing a neural network suitable to map (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms as inputs to (ii) historical incidences of responses to therapies for diseases of the individual organisms as outputs; and

2) training the constructed neural network on numerous examples of (i) genomic data as corresponds to (ii) historical incidences of responses to therapies for the diseases of, a multiplicity of individual organisms so as to make a trained neural network that is fit, and that possesses a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms; and

3) exercising the trained constructed neural network in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the neural network was trained, in order to identify a relationship between the particular therapy and genomic data, in the form of two or more alleles, of the organisms.

14. (Amended) The method according to claim 11

wherein the training is automated by computerized programmed operations using a genetic algorithm.

15. (Amended) The method according to claim 11

wherein the training is automated by computerized programmed operations using a genetic algorithm reduced in computational complexity by including the steps of:

grouping alleles and/or characteristic SNP patterns into families as are defined by (i) having similar expression patterns or (ii) being turned on and off by another gene, or (iii) both having similar expression patterns and being turned on and off by the same gene; and

starting training of the neural network with the genetic algorithm by using the families so created as single inputs to the neural network, the training with the genetic algorithm continuing repetitively until, families of greater and lessor significance being identified, it becomes computationally possible to train the neural network to genomic data consisting of individual alleles and/or characteristic SNP patterns;

wherein partitioning of all alleles and/or characteristic SNP patterns into families permits training of the neural network in a hierarchy of stages, first to the families and only then to the individual alleles and/or characteristic SNP patterns.

27. (Added) The method according to claim 11 that, at a time before the training of the constructed neural network on numerous examples further comprises:

obtaining, as a first portion of the numerous examples upon which the constructed neural network is trained, (i) genomic data in the form of alleles datums of types taken from a first group consisting essentially of

entire gene families,
specific alleles,
specific base pair sequences,
locations and types of introns, and

nucleotide polymorphism,

plus at least one member of a second, environmental, group consisting essentially of

diet type,
home region,
occupation,
viral levels,
peptide levels,
blood plasma levels, and
pharmacokinetic and pharmacodynamic parameters.

28. (Added) The method according to claim 27 wherein the obtaining, as a first portion of the numerous examples upon which the neural network is trained, (i) genomic data in the form of alleles datums from a third, combination genetic and environmental, group consisting essentially of

ethnicity, and
race.

29. (Added) A computerized method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism, the method comprising:

constructing a neural network relating as inputs (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms to outputs in the form of (ii) historical incidences of responses to therapies for diseases of the same individual organisms; and

training the neural network so constructed on numerous (i) genomic datums, as correspond to (ii) historical incidences of responses to therapies for the diseases, of a multiplicity of individual organisms;

therein making a trained neural network that is fit, and that possesses a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms; and

exercising the trained constructed neural network in respect

of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the neural network was trained, in order to identify a relationship between a particular therapy and the genomic data, in the form of two or more alleles, of an individual organism;

wherein from the identified relationship it is determinable whether the particular therapy is suitable for the individual organism.

30. (Added) A neural network

suitable to map (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms as inputs to (ii) historical incidences of responses to therapies for diseases of the individual organisms as outputs; and

trained on numerous examples of (i) genomic data as corresponds to (ii) historical incidences of responses to therapies for the diseases of, a multiplicity of individual organisms so as to be fit, and to possesses a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms;

wherein the trained neural network is exercisable in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the neural network was trained, in order to identify a relationship between the particular therapy and genomic data, in the form of two or more alleles, of the organisms.

31. (Added) The trained neural network according to claim 30

trained by computerized programmed operations using a genetic algorithm.

32. (Added) The trained neural network according to claim 30

trained by computerized programmed operations using a genetic algorithm is reduced in computational complexity by including the steps of:

grouping alleles and/or characteristic SNP patterns into

families as are defined by (i) having similar expression patterns or (ii) being turned on and off by another gene, or (iii) both having similar expression patterns and being turned on and off by the same gene; and

starting training of the neural network with the genetic algorithm by using the families so created as single inputs to the neural network, the training with the genetic algorithm continuing repetitively until, families of greater and lessor significance being identified, it becomes computationally possible to train the neural network to genomic data consisting of individual alleles and/or characteristic SNP patterns;

wherein partitioning of all alleles and/or characteristic SNP patterns into families permits training of the neural network in a hierarchy of stages, first to the families and only then to the individual alleles and/or characteristic SNP patterns.

33. (Added) The trained neural network according to claim 30 that is trained on the numerous examples

obtained, in a first portion, from (i) genomic data in the form of alleles datums of types taken from a first group consisting essentially of

entire gene families,
specific alleles,
specific base pair sequences,
locations and types of introns, and
nucleotide polymorphism,

plus at least one member of a second, environmental, group consisting essentially of

diet type,
home region,
occupation,
viral levels,
peptide levels,
blood plasma levels, and
pharmacokinetic and pharmacodynamic parameters.

34. (Added) The trained neural network according to claim 33 that is trained on the numerous examples

further obtained, still in the first portion, from (i) genomic data in the form of alleles datums of types taken from a third, combination genetic and environmental, group consisting essentially of

ethnicity, and

race.

35. (Added) A neural network functioning to identify from the genomic data of an individual organism a suitable therapy for at least one disease of the organism, the neural network

relating as inputs (i) genomic data in the form of two or more alleles and/or SNP patterns of individual organisms to outputs in the form of (ii) historical incidences of responses to therapies for diseases of the same individual organisms; and

being trained on numerous (i) genomic datums, as correspond to (ii) historical incidences of responses to therapies for the diseases, of a multiplicity of individual organisms; and, by virtue of so relating and of being sot trained

being fit, meaning possessing a measure of goodness, to map (i) said genomic data to (ii) incidences of responses to therapies for the diseases of the organisms when exercised in respect of a particular therapy for a particular disease, taken from among the therapies and the diseases to which the training was directed, in order to identify a relationship between a particular therapy and the genomic data, in the form of two or more alleles, of an individual organism;

wherein from exercising of the trained neural network possessing the measure of goodness on the identified relationship it is determinable whether the particular therapy is suitable for the individual organism.